

LABEL FILED: May 26, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about July 17, 1953, and February 3, 10, and 18, 1954, by the Vitamix Corp., from Philadelphia, Pa.

PRODUCT: 28 vials of *anterior pituitary solution*, 64 vials of *Vitopit*, 47 vials of *suprarenal cortex solution*, and 468 vials of *Multiglands* at Detroit, Mich. The size of each vial was 30 cc.

Analyses showed that the *suprarenal cortex solution* and the *Multiglands* contained no significant quantity of protein.

LABEL, IN PART: (Vial) "30 cc. Multiple Dose Vial Anterior Pituitary Solution Sterile—Intramuscular Only * * * Each cc. contains the water soluble extraction of dried glands derived from: Anterior Pituitary, fresh gland 18½ grains"; "30 cc. Multiple Dose Vial Vitopit * * * Intramuscular Only * * * Each 2 cc. represents the water soluble extraction of dried glands derived from: Anterior Pituitary fresh gland. . . . 18½ grs. Ovarian Whole Gland fresh gland. . . . 40 grs. Procaine HCl. . . . 1%"; "30 cc. Multiple Dose Vial Suprarenal Cortex Solution Sterile—Intramuscular Only For Professional Use Only * * * Each cc. contains a water soluble extract of 2.5 gram of fresh Suprarenal Cortex Tissue * * * Indications: Foreign Protein Therapy"; and "30 cc. Multiple Dose Vial Multiglands (Plurigland Extract) Intramuscular Only * * * Each 2 cc. represents the water soluble extraction of dried glands derived from: Suprarenal Cortex, fresh gland. . . . 3.0 grs. Thyroid U. S. P. . . . 2.0 grs. Pituitary Anterior, fresh gland. . . . 1.0 grs. Pituitary Posterior, fresh gland. . . . 0.1 grs. Ovarian Substance, fresh gland. . . . 15.0 grs. Thymus, fresh gland. . . . 3.0 grs. Lymphatic, fresh gland. . . . 3.0 grs. * * * Indications: Non-Specific Protein Therapy."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

Further misbranding, Section 502 (a), the statement "Indications: Foreign Protein Therapy" on the label of the *suprarenal cortex solution* and the statement "Indications: Non-Specific Protein Therapy" on the label of the *Multiglands* were false and misleading since such statements represented and suggested that the articles were effective for providing foreign protein reaction therapy, which was contrary to fact.

DISPOSITION: July 13, 1954. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

4470. Misbranding of anterior pituitary extract. U. S. v. 297 Boxes * * *.
(F. D. C. No. 36424. Sample No. 81734-L.)

LABEL FILED: March 18, 1954, District of Nebraska.

ALLEGED SHIPMENT: On or about April 23, 1952, from Chicago, Ill.

PRODUCT: 297 boxes, each containing 1 vial, of *anterior pituitary extract* at Lincoln, Nebr., in possession of Norden Laboratories.

RESULTS OF INVESTIGATION: The product was shipped in bulk from Chicago, Ill., and after its receipt by the consignee, it was repackaged and relabeled.

LABEL, IN PART: (Box) "Norden 10 cc Size Aqueous Extract of Anterior Pituitary"; (vial) "10 cc Size Aqueous Extract of Anterior Pituitary Caution: To be dispensed only by or on the prescription of a veterinarian. Packaged for Norden Laboratories Lincoln, Nebraska Each cc contains water-soluble extractives from 18½ grains fresh tissue. Chlorobutanol (Preserva-

tive), 0.5% * * * Dosage: Horses and Cattle, 5 to 10 cc; Sheep and Swine, 2 to 4 cc; Small Animals, $\frac{1}{2}$ to 2 cc, depending upon size. Inject subcutaneously or intramuscularly B 319."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 2, 1954. Default decree of condemnation and destruction.

4471. Misbranding of anterior pituitary extract and ovarian residue extract.

U. S. v. 1,463 Vials, etc. (F. D. C. No. 36807. Sample Nos. 15904-L, 15905-L.)

LIBEL FILED: On or about May 28, 1954, Western District of Missouri.

ALLEGED SHIPMENT: On or about February 26 and July 8, 1953, and March 7 and 31, 1954, from Chicago, Ill.

PRODUCT: 1,463 vials of *anterior pituitary extract* and 651 vials of *ovarian residue extract* at Kansas City, Mo., in possession of Jensen-Salsbery Labs., Inc. Some of the vials were labeled and some were unlabeled.

RESULTS OF INVESTIGATION: The products had been shipped in bulk from Chicago, Ill., and upon receipt by the consignee, they had been repackaged and, in part, relabeled.

LABEL, IN PART: (Vial) "Anterior Pituitary Extract 10 cc. Jen-Sal * * * Prepared from the fresh Anterior Pituitary Lobe, each cc. representing 18 $\frac{1}{2}$ gr. of gland substance. Preserved with 0.5% Chlorobutanol (Chloroform derivative). Packaged By Jensen-Salsbery Laboratories, Inc. Kansas City, Missouri * * * No claim is made for hormonal activity. Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian," and "Ovarian Residue Extract 25 cc. Jen-Sal * * * Concentrated An aqueous solution, each cc. representing the water soluble extractives from 40 grs. (2.6 Gms.) of fresh ovarian residue. Chlorobutanol 0.5% as a preservative Sold exclusively to veterinarians. Packaged By Jensen-Salsbery Laboratories, Inc. Kansas City, Missouri."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 9, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4472. Adulteration and misbranding of phenobarbital tablets. U. S. v. 420,000 Tablets * * *. (F. D. C. No. 36545. Sample No. 80521-L.)

LIBEL FILED: May 3, 1954, District of New Jersey.

ALLEGED SHIPMENT: On or about April 15, 1954, from Philadelphia, Pa. This was a return shipment.

PRODUCT: 420,000 *phenobarbital tablets* in 2 drums at Hoboken, N. J. Analysis showed that the product contained 74.4 percent of the declared amount of phenobarbital.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely $\frac{1}{4}$ grain of phenobarbital per tablet.